

K120710

Toshiba America Medical Systems, Inc.
Pre-market Notification 510(k)
TSX-302A/2, Aquilion Prime CT System

APR - 6 2012

510(k) Summary

Date: March 6, 2012

Manufacturer: Toshiba Medical Systems Corporation
1385 Shimoishigami, Otawara-shi,
Tochigi-ken, 324-8550, Japan

Initial Importer/Distributor: Toshiba America Medical Systems, Inc.
Address: P.O. Box 2068, 2441 Michelle Drive,
Tustin, CA 92781-2068

Contact: Paul Biggins, Director Regulatory Affairs
(714)730-5000

Establishment Registration Number: 2020563

Device Proprietary Name: TSX-302A/2, Aquilion Prime

Common Name: Scanner, Computed Tomography, X-Ray

Classification: 90-JAK

Regulatory Class: II (per 21 CFR 892.1750)

Performance Standard: None

Predicate Device(s): Toshiba TSX-302A, k110066

Reason for Submission Modification to cleared device

Description of this Device:

The TSX-302A/2 is a 40-row CT System that is intended to produce axial scans of the whole body to include the head. The TSX-302A/2 is based upon the technology and materials of previously marketed Toshiba CT systems.

Toshiba America Medical Systems, Inc.
Pre-market Notification 510(k)
TSX-302A/2, Aquilion Prime CT System

Summary of Intended Uses:

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head.

The Aquilion Prime has the capability to provide volume sets. These volume sets can then be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

Substantial Equivalence:

This device is substantially equivalent to the predicate devices which are commercially available at this time.

Toshiba Aquilion PRIME TSX-302A; k10066

Safety:

This device is designed and manufactured under ISO-13485 to include meeting the requirements of 21 CFR 820. Additionally this system is designed and manufactured in conformance with the appropriate IEC safety standards. This includes the employment of risk mitigation during the development of this device.

Radiation safety is assured by meeting the associated requirements of 21 CFR 1020. This information is provided to the FDA in compliance with the required CT product reports.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation, JAPAN
% Mr. Paul Biggins
Director Regulatory Affairs/US Agent
Toshiba America Medical Systems, Inc.
2441 Michelle Dr.
TUSTIN CA 92780

APR - 6 2012

Re: K120710
Trade/Device Name: TSX-302A/2, Aquilion Prime CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, IYO, and ITX
Dated: March 6, 2012
Received: March 8, 2012

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

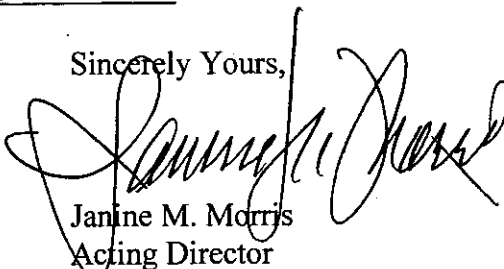
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803); please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: TSX-302A/2, Aquilion Prime CT System

Indications for Use:

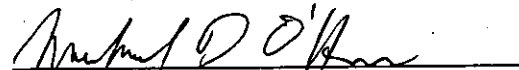
This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion PRIME has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

Prescription Use ☒ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K129710

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